UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/835,096	04/12/2001	Jay M. Short	INVIT1250-5	2970

28213 7590 06/13/2003

GRAY CARY WARE & FREIDENRICH LLP
4365 EXECUTIVE DRIVE
SUITE 1100
SAN DIEGO, CA 92121-2133

EXAMINER
TRAN, MY CHAU T

ART UNIT	PAPER NUMBER
1639	4

DATE MAILED: 06/13/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/835,096	Applicant(s) SHORT, JAY M.	
	Examin r My-Chau T. Tran	Art Unit 1639	

-- The MAILING DATE of this c mmunication appears on the c ver sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-84 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-84 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

(1). Claims 1, 3-26, 28-29, 31-48, and 77, drawn to a method for identifying a complex (a morphatide) from a library of complexes (morphatides) wherein the morphatide comprises a scaffolding component, a linker component, and an agent molecule, classified in class 435, subclass 7.1.

(2). Claims 2-11, 13-21, 24, 26-27, 30, and 33-48, drawn to a method for identifying a complex (a morphatide) from a library of complexes (morphatides) wherein the morphatide comprises a scaffolding component and an agent molecule (*Note this method differ from Group I, by not reciting a linker*), classified in class 435, subclass 6.

(3). Claim 49, drawn to a method of creating a mimic of the identified morphatide, classified in class 436, subclass 55.

(4). Claim 50, drawn to a method of separating scaffolding components with attached linker components from the agent molecules of the previously identified morphatide, classified in class 435, subclass 3.

(5). Claims 51-53, and 55-59, drawn to a method of identifying a presence of a substance in a sample from a subject, classified in class 435, subclass 4.

(6). Claim 54, drawn to a method of diagnosing a subject, classified in class 424, subclass 9.1.

(7). Claims 60, and 62, drawn to a morphatide capable of reacting with multiple types of molecules, classified in class 536, subclass 23.1.

(8). Claims 61 and 62, drawn to a morphatide capable of reacting with one type of molecules, classified in class 530, subclass 300.

(9). Claim 63, drawn to a composition comprising a morphatide and a pharmaceutically acceptable carrier, classified in numerous subclasses of classes 532-570 series depending on the structure of the molecule.

(10). Claim 64, drawn to a method of administering a composition of morphatide, classified in class 424, subclass 184.1.

(11). Claims 65-66, 67, 70-71, and 74, drawn to a composition comprising a morphatide conjugated to a therapeutic agent, classified in numerous subclasses of classes 514 series depending on the structure of the molecule.

(12). Claims 68-69, drawn to a morphatide labeled with a detectable marker, classified in class 436, subclass 56.

(13). Claim 72, drawn to a method of treating a subject with a composition of morphatide, classified in class 514, subclass 1.

(14). Claim 73, drawn to a method of drug delivery to a target in a body of the subject, classified in class 514, subclass 44.

(15). Claims 75-76, drawn to a method of drug delivery to a target in a body of the subject wherein the morphatide is incapable of being degraded, classified in class 424, subclass 78.08.

(16). Claim 78, drawn to a morphatide identified with the method step of separating the morphatides, classified in numerous subclasses of classes 532-570 series depending on the structure of the molecule.

(17). Claim 79, drawn to a morphatide identified with the method step of generating modified scaffolding, classified in numerous subclasses of classes 532-570 series depending on the structure of the molecule.

(18). Claim 80, drawn to a morphatide identified with the method step of separating the scaffolding components, classified in numerous subclasses of classes 532-570 series depending on the structure of the molecule.

(19). Claim 81, drawn to a morphatide identified with the method step of using sexual PCR fragment and reassemble the nucleic acid sequences, classified in numerous subclasses of classes 532-570 series depending on the structure of the molecule.

(20). Claim 82, drawn to a method of increasing the binding affinity of a morphatide with the method step of generating modified scaffolding, classified in class 436, subclass 85.

(21). Claim 83, drawn to a method of increasing the binding affinity of a morphatide with the method step of performing a suitable number of cycles of error prone PCR, classified in class 436, subclass 86.

(22). Claim 84, drawn to a method of increasing the binding affinity of a morphatide with the method step of separating morphatides with increase binding affinity for the target, classified in class 436, subclass 91.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions of Groups 1-6, 10, 13-15, and 20-22 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions as claimed have different method steps that have different functions, different effects, and modes of operation.

The method step of preparing a library of morphatides comprised of a scaffolding component, a linker component, and an agent molecules of Group 1 is not required by the claims of Groups 2-6, 10, 13-15, and 20-22. The method step of preparing a library of morphatides comprised of a scaffolding component and an agent molecule of Group 2 is not required by the claims of Groups 1, 3-6, 10, 13-15, and 20-22. The method step of creating a mimic of the identified morphatide of Group 3 is not required by the claims of Groups 1-2, 4-6, 10, 13-15, and 20-22. The method step of reattaching agent molecules to the new scaffolding components of Group 4 is not required by the claims of Groups 1-3, 5-6, 10, 13-15, and 20-22. The claims of Groups 1-4, 6, 10, 13-15, and 20-22 does not require the method step of forming a complex between the morphatide and the substance present in the sample of Group 5. The claims of Groups 1-5, 10, 13-15, and 20-22 does not require the method step wherein the detection of the complex is indicative of a disease of Group 6. The claims of Groups 1-6, 13-15, and 20-22 does not require the method step of administering a composition of Group 10. The claims of Groups 1-6, 10, 14-15, and 20-22 does not require the method step of treating a subject with a composition of Group 13. The claims of Groups 1-6, 10, 13, 15, and 20-22 does not require the method step of drug delivery to a target in a body of the subject of Group 14. The claims of

Groups 1-6, 10, 13-14, and 20-22 does not require the method step of drug delivery to a target in a body of the subject wherein the morphatide is incapable of being degraded of Group 15. The claims of Groups 1-6, 10, 13-15, and 21-22 does not require the method step of generating modified scaffolding component of Group 20. The method step of performing a suitable number of cycles of error prone PCR of Group 21 is not required by the claims of Groups 1-6, 10, 13-15, and 20, 22. The method step of separating morphatides with increase binding affinity for the target of Group 22 is not required by the claims of Groups 1-6, 10, 13-15, and 20-21.

3. Inventions of Groups 7-9, 11-12, and 16-19 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions as claimed have different functions and different effects.

The morphatide that is capable of reacting with multiple types of molecules of Group 7 is not required by the claims of Groups 8-9, 11-12, and 16-19. The morphatide capable of reacting with one type of molecules of Group 8 is not required by the claims of Groups 7, 9, 11-12, and 16-19. A composition comprising a morphatide and a pharmaceutically acceptable carrier of Group 9 is not required by the claims of Groups 7-8, 11-12, and 16-19. A composition comprising a morphatide conjugated to a therapeutic agent of Group 11 is not required by the claims of Groups 7-9, 12, and 16-19. The a morphatide labeled with a detectable marker of Group 12 is not required by the claims of Groups 7-9, 11, and 16-19. The morphatide identified with the method step of separating the morphatides of Group 16 is not required by the claims of

Groups 7-9, 11-12, and 17-19. The morphatide identified with the method step of separating the morphatides of Group 17 is not required by the claims of Groups 7-9, 11-12, 16, and 18-19. The morphatide identified with the method step of generating modified scaffolding of Group 18 is not required by the claims of Groups 7-9, 11-12, 16-17, and 19. The morphatide identified with the method step of separating the scaffolding components of Group 19 is not required by the claims of Groups 7-9, 11-12, and 16-18.

4. Inventions of Groups 5-7, 9-10, and 14-17 (products) and Groups 1-3, and 18-20 (processes) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product (a morphatide) as claimed can be used in a materially different process of using that product. For example a "morphatide" consisting of a lipid scaffold, an ethanolamine linker a fluorescent agent molecule could be used as a probe for membrane fluidity measurements or a morphatide.

5. Inventions Groups 5-7, 9-10, and 14-17 (products) and Groups 4, 8, and 11-13 (processes) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant

case the product as claimed can be used in a materially different process such as identification of a substance in a sample.

6. Because these inventions are distinct for the reasons given above and the searches required are not co-extensive thus requiring a burdensome search, restriction for examination purposes as indicated is proper. Additionally, different patentability considerations are involved for each group. For example, a patentability determination for Group 7 would involve a determination of the patentability of the combination of a composition comprised of a morphatide and a pharmaceutically acceptable carrier (independent of its use) while a patentability determination for Group 13 would involve a consideration of the patentability of the a method of drug delivery to a target in a body of the subject wherein the morphatide is incapable of being degraded. These considerations are very different in nature.

Even though some of the groups are classified in the same class/subclass, this has no effect on the non-patent literature search. Different groups would require completely different searches in non-patent databases, and there is no exception that the searches would be co-extensive.

7. This application contains claims directed to the following patentably distinct species of the claimed invention.

8. If applicants elect the invention of **Group 1 (Claims 1, 3-26, 28-29, 31-48, and 77)**, applicants are required to further elect ***one*** species from ***each*** of the following group of species:

a. One single species of a scaffold. (Applicants are requested to ***provide the structure or sequence, reciting the "fixed region" and the "randomized region" of the elected scaffold***)

b. Specific "linker" and number of "linkers". (Applicants are requested to ***provide the structure of the "linker"***)

c. Specific "agent" and number of "agent". (Applicants are requested to ***provide the structure of the "agent"***)

d. One single species of target.

e. Specific mode of interaction with the target.

f. Specific mode of separating the "morphatide".

Base on the election of species (a), (b), and (c) the selection of the number and/or type of "linker" and/or "agent" must include the point and/or means of attachment to a particular scaffold that would results in a morphatide.

The selection of the number and/or type of "linker" and/or "agent" and the point and/or means of attachment to a particular scaffold results in a morphatide, which have different chemical structure and/or physiochemical properties and would be capable of separate manufacture and/or use; and would necessitate different and separately burdensome manual and computer bibliographic and structure searches in both patent and non-patent areas. Further for the different methods, the steps are different, requiring different reagents and/or producing different products/results.

Accordingly, applicants are hereby required to elect **a single morphatide composition with chemical structure** from among the compounds listed in the specification for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held allowable.

For this response to be complete and for search purposes, applicants should provide the chemical structure of elected compounds or composition or species, wherein each specific formula substituents of each of the above identified elected species are defined either by picture, or by expressing the species in terms of the variables of the formula.

9. If applicants elect the invention of **Group 2 (Claims 2-11, 13-21, 24, 26-27, 30, and 33-48)**, applicants are required to further elect ***one*** species from ***each*** of the following group of species:

a. One single species of a scaffold. (Applicants are requested to ***provide the structure or sequence, reciting the "fixed region" and the "randomized region" of the elected scaffold***)

b. Specific "agent" and number of "agent". (Applicants are requested to ***provide the structure of the "agent"***)

c. One single species of target.

d. One single mode of interaction with the target.

e. One single mode of separating the "morphatide".

Base on the election of species (a) and (b) the selection of the number and/or type of "linker" and/or "agent" must include the point and/or means of attachment to a particular scaffold that would results in a morphatide.

The selection of the number and/or type of "agent" and the point and/or means of attachment to a particular scaffold results in a morphatide, which have different chemical structure and/or physiochemical properties and would be capable of separate manufacture and/or use; and would necessitate different and separately burdensome manual and computer bibliographic and structure searches in both patent and non-patent areas. Further for the different methods, the steps are different, requiring different reagents and/or producing different products/results.

Accordingly, applicants are hereby required to elect **a single morphatide composition with chemical structure** from among the compounds listed in the specification for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held allowable.

For this response to be complete and for search purposes, applicants should provide the chemical structure of elected compounds or composition or species, wherein each specific formula substituents of each of the above identified elected species are defined either by picture, or by expressing the species in terms of the variables of the formula.

10. If applicants elect the invention of **Group 3 (Claim 49)**, applicants are required to further elect ***one*** species from ***each*** of the following group of species:

a. One single species of a scaffold. (Applicants are requested to ***provide the structure of the elected scaffold***)

b. Specific "linker" and number of "linkers". (Applicants are requested to ***provide the structure of the "linker"***)

c. Specific "agent" and number of "agent". (Applicants are requested to ***provide the structure of the "agent"***)

d. One single species of target.

e. Specific mode of interaction with the target.

Base on the election of species (a), (b), and (c) the selection of the number and/or type of "linker" and/or "agent" must include the point and/or means of attachment to a particular scaffold that would results in a morphatide.

The selection of the number and/or type of "linker" and/or "agent" and the point and/or means of attachment to a particular scaffold results in a morphatide, which have different chemical structure and/or physiochemical properties and would be capable of separate manufacture and/or use; and would necessitate different and separately burdensome manual and computer bibliographic and structure searches in both patent and non-patent areas. Further for the different methods, the steps are different, requiring different reagents and/or producing different products/results.

Accordingly, applicants are hereby required to elect **a single morphatide composition with chemical structure** from among the compounds listed in the specification for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held allowable.

For this response to be complete and for search purposes, applicants should provide the chemical structure of elected compounds or composition or species, wherein each specific formula substituents of each of the above identified elected species are defined either by picture, or by expressing the species in terms of the variables of the formula.

11. If applicants elect the invention of **Group 4 (Claim 50)**, applicants are required to further elect ***one*** species from ***each*** of the following group of species:

a. One single species of a scaffold. (Applicants are requested to ***provide the structure of the elected scaffold***)

b. Specific "linker" and number of "linkers". (Applicants are requested to ***provide the structure of the "linker"***)

c. Specific "agent" and number of "agent". (Applicants are requested to ***provide the structure of the "agent"***)

e. One single species of target.

f. Specific mode of interaction with the target.

g. One single species of "linker" for separating the scaffold (regarding step (a) of Claim 50).

h. One single species of "linker" for combining the scaffold (regarding step (b) of Claim 50).

i. One single species "agent" for reattachment (regarding step (b) of Claim 50).

Base on the election of species (a), (b), and (c) the selection of the number and/or type of "linker" and/or "agent" must include the point and/or means of attachment to a particular scaffold that would results in a morphatide.

The selection of the number and/or type of "linker" and/or "agent" and the point and/or means of attachment to a particular scaffold results in a morphatide, which have different chemical structure and/or physiochemical properties and would be capable of separate manufacture and/or use; and would necessitate different and separately burdensome manual and

computer bibliographic and structure searches in both patent and non-patent areas. Further for the different methods, the steps are different, requiring different reagents and/or producing different products/results.

Accordingly, applicants are hereby required to elect **a single morphatide composition with chemical structure** from among the compounds listed in the specification for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held allowable.

For this response to be complete and for search purposes, applicants should provide the chemical structure of elected compounds or composition or species, wherein each specific formula substituents of each of the above identified elected species are defined either by picture, or by expressing the species in terms of the variables of the formula.

12. If applicants elect the invention of **Group 5 (Claims 51-53, and 55-59)**, applicants are required to further elect ***one*** species from ***each*** of the following group of species:

a. Specific label for detection.

b. Specific mode of interaction with the "morphatide".

c. Specific "sample" for detection.

d. Specific analyte of detection (i.e. "substance").

The species are distinct, each from the other, because their structures and/or modes of action are different. For the different methods, the steps are different, requiring different reagents and/or producing different products/results. Therefore, the species have different issues regarding patentability and represent patentably distinct subject matter.

For this response to be complete and for search purposes, applicants should provide the chemical structure of elected compounds or composition or species, wherein each specific formula substituents of each of the above identified elected species are defined either by picture, or by expressing the species in terms of the variables of the formula.

13. If applicants elect the invention of **Group 10 (Claim 64)**, applicants are required to further elect ***one*** species from ***each*** of the following group of species:

a. A ***single*** type of administration.

The species are distinct, each from the other, because their modes of action are different. For the different methods, the steps are different, requiring different reagents and/or producing different products/results. Therefore, the species have different issues regarding patentability and represent patentably distinct subject matter.

For this response to be complete and for search purposes, applicants should provide the chemical structure of elected compounds or composition or species, wherein each specific formula substituents of each of the above identified elected species are defined either by picture, or by expressing the species in terms of the variables of the formula.

14. If applicants elect the invention of **Group 11 (Claims 65-67, 70-71 and 74)**, applicants are required to further elect ***one*** species from ***each*** of the following group of species:

a. A ***single*** type of therapeutic agent.

The species are distinct, each from the other, because their modes of action are different. For the different methods, the steps are different, requiring different reagents and/or producing

different products/results. Therefore, the species have different issues regarding patentability and represent patentably distinct subject matter.

For this response to be complete and for search purposes, applicants should provide the chemical structure of elected compounds or composition or species, wherein each specific formula substituents of each of the above identified elected species are defined either by picture, or by expressing the species in terms of the variables of the formula.

15. If applicants elect the invention of **Group 12 (Claims 68-69)**, applicants are required to further elect ***one*** species from ***each*** of the following group of species:

a. Specific "marker".

The species are distinct, each from the other, because their modes of action are different. For the different methods, the steps are different, requiring different reagents and/or producing different products/results. Therefore, the species have different issues regarding patentability and represent patentably distinct subject matter.

For this response to be complete and for search purposes, applicants should provide the chemical structure of elected compounds or composition or species, wherein each specific formula substituents of each of the above identified elected species are defined either by picture, or by expressing the species in terms of the variables of the formula.

16. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable

thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

17. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

18. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to My-Chau T. Tran whose telephone number is 703-305-6999.

The examiner is on ***Increased Flex Schedule*** and can normally be reached on Monday: 8:00-2:30; Tuesday-Thursday: 7:30-5:00; Friday: 8:00-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew J. Wang can be reached on 703-306-3217. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1123.

mct
June 11, 2003

PADMASHRI PONNALURI
PRIMARY EXAMINER